Remarks

Claims 11, 15 and 20-25 were pending and examined in this application. With the above amendments, claims 20, 25 and 31 are canceled and claims 11, 15, and 30 are amended, to more particularly point out and distinctly claim the invention. The claim cancellations and amendments are made without prejudice or disclaimer.

Applicants respectfully request reconsideration and withdrawal of the current rejections based on the amendments and the following remarks.

Rejections under 35 U.S.C. 112, first paragraph

Claims 11, 15 and 20-30 stand rejected under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement. Withdrawal of these rejections are respectfully requested for the following reasons.

Regarding the assertion that the specification does not enable methods of monitoring the progression of any disease or disorder resulting from HIV infection, Applicants note that the claims as amended are directed to monitoring the progression of HIV infection or AIDS (claims 11, 21-24, 30 and 32-35) or assessing the effectiveness of a treatment for HIV infection or AIDS (claims 15 and 26-29), and not any disease or disorder resulting from HIV infection.

The PTO also asserts that the specification fails to establish any correlation between the number of pDC2 cells and the progression of AIDS or HIV infection. However, the skilled artisan would understand that the specification does establish that correlation, since the Example at pages 28-top of page 32 establishes that pDC2 cells are the natural interferon-producing cells (see in particular Table 1), and the Example at pages 32-39 establish that interferon production negatively correlates with HIV progression and positively correlates with the effectiveness of HIV treatment (as determined by $CD4^+$ cell counts). Given this data, there can be no other conclusion to the skilled artisan than that the quantity of pDC2 cells negatively correlates with HIV progression and positively correlates with the effectiveness of HIV treatment. This correlation is sufficient to enable the claimed methods.

Although the PTO asserts that "most significant impairment to studies of IFN-α system in human peripheral blood remains the inability to identify the unique NIPC" (citing a 1993 article), the instant application identifies the unique NIPC as pDC2 cells. This is precisely a main point of this invention, along with the previously discussed correlations of HIV with pDC2 cells. Citing a 1993 article that describes an inability that is solved by the instant application should certainly not be used as a reason for asserting that the claims in the instant application are not enabled. The various studies suggested by the PTO regarding the tissue studies, developmental pathway and cellular distribution of NIPCs is also completely irrelevant to the enablement of the instant claims, because the specification has established that pDC2 cell numbers in peripheral blood correlate with effective HIV treatment and negatively correlate with HIV or AIDS progression. No amount of tissue studies, developmental pathway studies or cellular distribution studies can undo that correlation, and are therefore irrelevant with regard to the enablement of the instant claims. Thus, the PTO has failed to establish any reason to believe that the claimed methods are not enabled based on a lack of correlation between pDC2 cell numbers in peripheral blood and effective HIV treatment, and the negative correlation between pDC2 cell numbers and HIV progression.

The PTO also asserts that "it is highly unpredictable to predict the number of pDC2 (as claimed) by evaluating the levels of IFN-α produced in a sample." However, the instant claims are not directed to predicting the number of pDC2 cells by evaluating the levels of IFN-α produced in a sample. Rather, they are directed to monitoring HIV infection or AIDS, or assessing the effectiveness of an HIV or AIDS treatment. There is no requirement in any of the claims that the pDC2 cells are counted by evaluating the levels of IFN-α in the sample. The correlation established in the cited specification Examples were well controlled and clearly establish that pDC2 cells (as determined by cell sorting using established markers) are the NIPC and that IFN-α production negatively correlates with HIV and AIDS progression.

Regarding the concern that a reference range for a healthy population needs to be established and that pDC2 cells decrease with age, Applicants assert that it would take only routine experimentation to establish these controls for any individual. Such reference ranges could be established simply by drawing blood from the appropriate age-matched normal population and counting pDC2 cells using, e.g., the cell sorting methods established in the instant specification. Such a determination would certainly not be considered undue experimentation, since there is no uncertainty in the methods used to make those determinations. The skilled artisan would also certainly know that a control number must be established using the appropriate population that most closely matches the patient, except for the presence of HIV. Only routine experimentation is therefore required to obtain a control count for any patient. Applicants also note that claims 15 and 26-29 do not require a control sample, but only a sample from the patient before treatment. The concern about the control samples is thus completely irrelevant to claims 15 and 26-29.

In light of the claim amendments and the above discussion, Applicants respectfully request withdrawal of the enablement rejections under 35 U.S.C. 112, first paragraph.

Conclusion

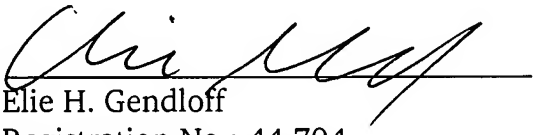
Based on the claim amendments and the above discussion, Applicants respectfully request withdrawal of all rejections and passage of the claims to allowance. If there are any minor matters that prevent allowance of the claims, the PTO may contact the undersigned attorney to resolve those matters.

It is believed that no fee is required with this Amendment and Reply. If there are any unanticipated fees required to maintain pendency of this application, those fees can be withdrawn from Deposit Account No. 01-1785.

Respectfully submitted

AMSTER, ROTHSTEIN & EBENSTEIN LLP
Attorneys for Applicant
90 Park Avenue
New York, NY 10016
(212) 336-8000

Dated: New York, New York
November 9, 2004

By: 
Elie H. Gendloff
Registration No.: 44,704